

## 2. 510(k) Summary

**Submitted by:** Merete Medical GmbH  
Alt Lankwitz 102,  
12247 Berlin, Germany

**FDA Registration Number:** 3002949614

**Contact Person:** Emmanuel Anapliotis  
Merete Medical, Inc.  
49 Purchase Street  
Rye, New York 10580  
Phone: 914 967 1532

**Device Name:** Merete Locking Bone Plate System II

**Device Classification:** 21 CFR 888.3030 Single/multiple component  
Metallic bone fixation appliances and accessories

**Product Code:** KTT

**Proposed Regulatory Class:** Class II

### Predicate Device:

- Merete Locking Bone Plate System – K090063
- Merete MetaFix Small Fragment Bone Plate – K050457
- Merete BLP™ Small Fragment Locking Bone Plate System – K063487
- Merete 3.0 mm and 3.5 mm Locking Screws – K081513
- DARCO Locking Plate System – K061808

### Device Description:

The Merete Locking Bone Plate System II consists of contoured, anatomically shaped locking bone plates in various sizes and different curvatures for Merete 3.0mm and 3.5mm locking screws (K081513) and cannulated 3.0mm compression screws (K090063). The system is made of titanium alloy Ti-6Al-4V and unalloyed titanium.

### Intended use:

The Merete Locking Bone Plate System II can be used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes.

### Technological Characteristics:

The components of the Merete Locking Bone Plate System II are similar to legally marketed predicate device listed above in that they share similar indications for use,

are manufactured from similar materials and incorporate similar technological characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Merette Medical GmbH  
% Merete Medical, Inc.  
Mr. Emmanuel Anapliotis  
49 Purchase Street  
Rye, New York 10580

DEC - 3 2010

Re: K102688

Trade/Device Name: Merete Locking Bone Plate System II

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: KTT

Dated: September 14, 2010

Received: September 17, 2010

Dear Mr. Anapliotis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

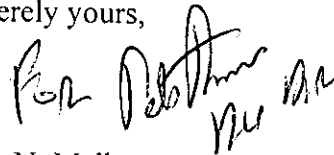
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

1. Indications for Use Statement

DEC - 3 2010

Indications for Use

510(k) Number (if known): K102688 (pg 1/1)

Device Name: Merete Locking Bone Plate System II

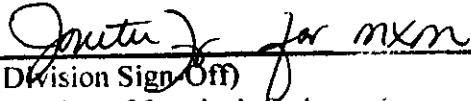
Indications for Use:

The Merete Locking Bone Plate System can be used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K102688